

**IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION**

ASTRAZENECA PHARMACEUTICALS LP

PLAINTIFF

v.

Case No. 4:24-cv-00268-KGB

**ALAN MCCLAIN, in his official capacity
as Commissioner of the Arkansas
Insurance Department**

DEFENDANT

DALLAS COUNTY MEDICAL CENTER

INTERVENOR

ORDER

Pending before the Court are a motion for judgment on the pleadings filed by intervenor Dallas County Medical Center (“DCMC”) (Dkt. No. 84) and a motion to strike the declaration of Rand Booth filed by plaintiff AstraZeneca Pharmaceuticals LP (“AstraZeneca”) (Dkt. No. 103). AstraZeneca has responded, and DCMC and defendant Alan McClain, in his official capacity as Commissioner of the Arkansas Insurance Department (“Commissioner”), have replied (Dkt. Nos. 90, 102, 110). For the following reasons, the Court denies DCMC’s motion for judgment on the pleadings (Dkt. No. 84), and the Court denies as moot AstraZeneca’s motion to strike (Dkt. No. 103).

I. Background

This case arises out of the Arkansas legislature’s passage of Act 1103 of 2021 (“Act 1103”), Ark. Code Ann. § 23-92-601 *et seq.*, which addresses the delivery of 340B drugs to contract pharmacies in Arkansas. Section 340B is a federal prescription drug program that requires pharmaceutical manufacturers to provide qualified health care providers, referred to as “covered entities,” with pricing discounts on certain drugs prescribed to individuals and families whose income falls below the federal poverty level. 42 U.S.C. § 256b(a)(1); 42 U.S.C. § 1396r-8(a)(1). Covered entities have contracted with outside pharmacies for the distribution of 340B drugs. Act 1103 protects covered entities and their patients from drug manufacturers’ restrictions on the

number of contract pharmacies a covered entity can use and still receive discount pricing under the 340B plan. Ark. Code Ann. § 23-92-60.

In 2020, a number of pharmaceutical companies imposed restrictions and limitations on the distribution of Section 340B discounted drugs to contract pharmacies. *See, e.g., Sanofi Policy, SANOFI* (Feb. 1, 2021), https://340besp.com/sanofi-policy-2021-02-02-09_18_19.pdf. In response, the U.S. Department of Health and Human Services (“HHS”) issued an opinion stating that “covered entities under the 340B program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients.” *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 52 (D. Del. 2021). Further, HHS concluded that the “plain meaning” of Section 340B precluded participating pharmaceutical companies from restricting or otherwise limiting contracts between covered entities and outside, retail pharmacies. *Id.* at 52–53. AstraZeneca and other pharmaceutical companies challenged HHS’s contract pharmacy opinion and prevailed in the Third Circuit in *Sanofi Aventis U.S. LLC v. U.S. Dep’t of Health and Human Services*, 58 F.4th 696 (3d Cir. 2023). In that case, the Third Circuit held that Section 340B is silent with respect to contract pharmacies and that, therefore, HHS lacked the statutory authority to issue its opinion restricting the ability of participating pharmaceutical companies to adopt policies on the distribution of discounted drugs to contract pharmacies. *Id.* at 703–06.

Arkansas enacted Act 1103, which “prohibits pharmaceutical manufacturers from interfering in a covered entity’s agreement with a contract pharmacy by denying the pharmacy access to a covered entity’s 340B drugs” and “prohibits pharmaceutical manufacturers from interfering in a covered entity’s agreement with a contract pharmacy by denying 340B drug pricing

to covered entities who use contract pharmacies for distribution.” *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024) (citing Ark. Code Ann. § 23-92-604).

In 2022, an association of pharmaceutical manufacturers sought an injunction against enforcement of Act 1103 on a theory that Section 340B preempts it. *Id.* at 1139–40. They mounted a facial, pre-enforcement challenge. This Court and the Eighth Circuit disagreed with the position advocated by the association of pharmaceutical manufacturers. *Id.* The Eighth Circuit held that “the 340B Program is not ‘so pervasive . . . that Congress left no room for the States to supplement it,’” given that the statute “‘is silent about delivery’ of drugs to patients.” *Id.* at 1143 (quoting *Sanofi Aventis*, 58 F.4th at 703) (other quotation marks and citation omitted). Additionally, because the Arkansas law “does not require manufacturers to provide 340B pricing discounts to contract pharmacies,” and “does not set or enforce discount pricing,” the Eighth Circuit found that “the delivery of a covered entity’s 340B drugs to contract pharmacies for dispensing creates no obstacle” to the statute’s purpose. *Id.* at 1145. In fact, the Eighth Circuit observed that the Arkansas law “assists in fulfilling the purpose of 340B” because it facilitates the distribution and dispensation of discounted 340B drugs. *Id.*

AstraZeneca’s operative complaint alleges three counts seeking declaratory relief that Act 1103 is unconstitutional and injunctive relief barring the enforcement of Act 1103 (Dkt. No. 25). AstraZeneca now maintains an as-applied, post-enforcement challenge. Count I alleges that Act 1103 is preempted by federal patent laws under the Supremacy Clause (*Id.*, ¶¶ 90–93). Count II alleges that Act 1103 violates the Contracts Clause of the U.S. Constitution (*Id.*, ¶¶ 94–99), and Count III alleges that Act 1103 violates the Takings Clause of the U.S. Constitution (*Id.*, ¶¶ 100–05).

AstraZeneca is a limited partnership organized under the laws of Delaware with its principal place of business in Wilmington, Delaware (*Id.*, ¶ 14). Commissioner is a resident of Arkansas who is responsible for administering and enforcing the provisions of Act 1103. (*Id.*, ¶ 15). DCMC is a nonprofit, government-funded hospital located in Fordyce, Arkansas (Dkt. No. 30, at 12). DCMC has been designated under the Medicare program as a critical access hospital (“CAH”) (*Id.*, at 11). Based on its CAH status, DCMC participates as a covered entity under the 340B program. (*Id.*, at 12).

In its motion for judgment on the pleadings, DCMC contends that AstraZeneca’s claims are barred by claim and issue preclusion because all of its claims could have been brought in the *PhRMA* case and because the issue of whether Act 1103 affects drug pricing was settled in the *PhRMA* case (Dkt. No. 84). AstraZeneca responds that DCMC and AstraZeneca were not involved in the previous litigation, nor were they in privity with any party there (Dkt. No. 90). Additionally, AstraZeneca contends that its claims in this case are different because those claims are based on how ACT 1103 is applied to contract pharmacy policies instead of a facial constitutional challenge (*Id.*).

DCMC argues that, even if AstraZeneca’s claims are not precluded, they fail as a matter of law (Dkt. No. 102). DCMC contends that Act 1103 is not preempted by federal patent laws because it does not adjust 340B drug prices as this Court has ruled and the Eighth Circuit has affirmed (*Id.*, at 19). DCMC next argues that AstraZeneca has not pleaded facts that would give rise to a basis for relief resulting from an alleged violation of the Contracts Clause (*Id.*, at 25). Finally, DCMC asserts that Act 1103 neither forcibly takes property from AstraZeneca nor is a regulatory taking (*Id.*, at 32).

II. Applicable Law

Federal Rule of Civil Procedure 12 provides that a party may seek judgment on the pleadings. Fed. R. Civ. P. 12(c). “A motion for judgment on the pleadings will be granted only where the moving party has clearly established that no material issue of fact remains and the moving party is entitled to judgment as a matter of law.” *Waldron v. Boeing Co.*, 388 F.3d 591, 593 (8th Cir. 2004) (citations omitted).

A motion under Federal Rule of Civil Procedure 12(c) is governed by the same standards as a motion under Federal Rule of Civil Procedure 12(b)(6): “a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Clemons v. Crawford*, 585 F.3d 1119, 1124 (8th Cir. 2009) (citing *Ashley Cnty., Ark. v. Pfizer*, 552 F.3d 659, 665 (8th Cir. 2009)). Further, the court “view[s] all facts pleaded by the nonmoving party as true and grants all reasonable inferences in favor of that party.” *Poehl v. Countrywide Home Loans, Inc.*, 528 F.3d 1093, 1096 (8th Cir. 2008) (citing *Syverson v. FirePond, Inc.*, 383 F.3d 745, 749 (8th Cir. 2004)). While the court’s review is generally limited to the pleadings in this context, the court may properly consider “matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint.” *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999).

III. Analysis

DCMC contends that AstraZeneca’s amended complaint should be barred by *res judicata*—both claim and issue preclusion (Dkt. No. 84, at 2). DCMC also maintains that AstraZeneca’s claims fail as a matter of law under the Federal Rule of Civil Procedure 12(c) standard (*Id.*, at 1).

A. Analysis Of Claim Or Issue Preclusion

Under federal common law, the doctrine of *res judicata* or claim preclusion, applies when: “(1) the first suit resulted in a final judgment on the merits; (2) the first suit was based on proper jurisdiction; (3) both suits involve the same parties (or those in privity with them); and (4) both suits are based upon the same claims or causes of action.” *Costner v. URS Consultants, Inc.*, 153 F.3d 667, 673 (8th Cir. 1998). “[W]hether two claims are the same for *res judicata* purposes depends on whether the claims arise out of the same nucleus of operative fact or are based upon the same factual predicate.” *Elbert v. Carter*, 903 F.3d 779, 782 (8th Cir. 2018) (quoting *Murphy v. Jones*, 877 F.2d 682, 684–85 (8th Cir. 1989)). Under the doctrine of *res judicata*, “a final judgment on the merits of an action precludes the parties or their privies from re-litigating issues that were or could have been raised in that action.” *Allen v. McCurry*, 449 U.S. 90, 94 (1980).

The doctrine of collateral estoppel, or issue preclusion, provides that “when an issue of ultimate fact has been determined by a valid and final judgment, that issue cannot again be litigated between the same parties in another lawsuit.” *United States v. Brekke*, 97 F.3d 1043, 1049 (8th Cir. 1996). Courts in the Eighth Circuit examine five factors to determine whether collateral estoppel applies to a particular case:

- (1) the party sought to be precluded in the second suit must have been a party, or in privity with a party, to the original lawsuit;
- (2) the issue sought to be precluded must be the same as the issue involved in the prior action;
- (3) the issue sought to be precluded must have been actually litigated in the prior action;
- (4) the issue sought to be precluded must have been determined by a valid and final judgment; and
- (5) the determination in the prior action must have been essential to the prior judgment.

Estrada-Rodriguez v. Lynch, 825 F.3d 397, 402 (8th Cir. 2016).

DCMC contends that all of AstraZeneca’s claims should have been brought in the *PhRMA* case (Dkt. No. 85, at 26). Further, DCMC argues that, since the issue of whether Act 1103 improperly regulates drug pricing was settled in *PhARMA*, the issue cannot be re-litigated here, so any claim that relies on the pricing issue should be dismissed (*Id.*, at 27). AstraZeneca disputes privity to the *PhRMA* parties and whether the claims and issues arise from the same causes of action and facts (Dkt No. 90).

As an initial matter, DCMC provided an affidavit from Commissioner’s counsel, Rand Booth, stating the Commissioner supports DCMC’s motion for judgment on the pleadings (Dkt. No. 102–1). AstraZeneca moves to strike the declaration (Dkt. No. 103). In response, DCMC concedes that the declaration “is not critical to [DCMC’s] motion, and in the interest of efficiency, [DCMC] agrees that this Court should disregard the Declaration in ruling on [DCMC]’s motion.” (Dkt. No. 110, at 2). Accordingly, the Court denies as moot the motion to strike (Dkt. No. 103). The Court will not consider the declaration in considering DCMC’s motion.

1. Privity

AstraZeneca contends that, since DCMC was not a party to the *PhRMA* litigation, DCMC cannot invoke that litigation as a basis for claim or issue preclusion in this case (Dkt. No. 90, at 22 (citing *United States v. Metropolitan St. Louis Sewer District*, 952 F.2d 1040 (8th Cir. 1992))). In response to AstraZeneca’s privity arguments regarding DCMC, DCMC contends that, even though it was not a party to *PhRMA v. McClain*, Case No. 4:21-cv-00864-BRW (Mar. 28, 2022) (“*PhRMA Case*”), it was in privity with the intervenors in the *PhRMA Case* (Dkt. No. 102, at 10–12).

Claim or issue preclusion may be raised by a nonparty that is in privity with a party to the original lawsuit. “[I]n certain limited circumstances” a nonparty to a prior suit may be considered

in privity with a party if the nonparty was “‘adequately represented’ by someone with the same interests who [wa]s a party” to the prior suit. *Midwest Disability Initiative v. JANS Enters., Inc.*, 929 F.3d 603, 607 (8th Cir. 2019) (citation omitted). This “adequate representation” requirement is satisfied if: (1) the interests of the two parties are aligned; and (2) the original party understood itself to be acting in a representative capacity. *Id.*

a. DCMC

The intervenors in the *PhRMA* Case were Community Health Centers of Arkansas and Piggott Community Hospital (“*PhRMA* Intervenors”). See *PhRMA v. McClain*, Case No. 4:21-cv-00864-BRW (Mar. 28, 2022), Dkt. No. 18, at 23. *PhRMA* Intervenors represented all of the safety net hospitals and clinics in Arkansas participating in the 340B program, which included the DCMC in this case. *Id.* *PhRMA* Intervenors successfully defended against a pre-enforcement facial challenge to the constitutionality of Act 1103 on preemption grounds. Based on the record in both cases, the Court determines that the interests of the *PhRMA* Intervenors and DCMC in this case are aligned and that the *PhRMA* Intervenors knowingly represented the interests of all Arkansas covered entities. *PhRMA* Intervenors satisfy the requirement of adequate representation for purposes of privity. Accordingly, this Court concludes that the *PhRMA* Intervenors and DCMC are in privity and that DCMC may invoke claim or issue preclusion despite not having been a party in the *PhRMA* Case.

b. AstraZeneca

The Court notes that AstraZeneca does not concede its privity with plaintiff in the *PhRMA* Case. AstraZeneca makes no substantive privity argument with respect to AstraZeneca’s relationship with plaintiff in the *PhRMA* Case in its pleadings. This Court proceeds to analyze

these legal issues assuming without deciding, and applying the same rationale as articulated with respect to DCMC, that AstraZeneca was in privity with plaintiff in the *PhRMA* Case.

2. Claims

In addition to a privity requirement, application of claim or issue preclusion depends on whether both suits are based on the same claims or causes of action: “a claim is barred by res judicata if it arises out of the same nucleus of operative facts as the prior claim.” *Yankton Sioux Tribe v. U.S. Dept. of Health and Human Servs.*, 533 F.3d 634, 641 (8th Cir. 2008) (quotation omitted); *see also Midwest Disability Initiative v. JANS Enters., Inc.*, 929 F.3d 603, 609–10 (8th Cir. 2019). “[W]hether two claims are the same for res judicata purposes depends on whether the claims arise out of the same nucleus of operative fact or are based upon the same factual predicate.” *Murphy v. Jones*, 877 F.2d 682, 684–85 (8th Cir. 1989).

Further, the issue sought to be precluded must have been actually litigated in the prior action for collateral estoppel to apply. To assess whether an issue has been “actually litigated,” the Eighth Circuit provides the following guidance:

The inquiry must always be as to the point or question actually litigated and determined in the original action, not what might have been thus litigated and determined. An issue lurking in the record but not raised or decided is not actually litigated. A party may choose not to litigate a particular issue for various reasons, including cost, strategy, and the difficulty of obtaining evidence.

We thus agree with other circuits that for an issue to be “actually litigated,” the issue must have been “raised, contested, and submitted for determination” in the prior proceeding, and it must be determined.

Fofana v. Mayorkas, 4 F.4th 668, 671 (8th Cir. 2021) (internal citations omitted).

DCMC contends that the operative fact in both cases is the passage of Act 1103; DCMC makes a facial argument. AstraZeneca asserts that the claims in the current case rely on more

than the passage of the law and include how the law is applied to AstraZeneca's specific policies in Arkansas; AstraZeneca makes an as-applied argument.

Upon review of AstraZeneca's claims, the Court determines that none of AstraZeneca's current claims are barred by claim or issue preclusion. All parties concede that the *PhRMA* Case was a pre-enforcement, facial challenge to Act 1103. Further, all parties acknowledge that this current suit involves a post-enforcement, as-applied challenge to Act 1103 by AstraZeneca against whom Act 1103 now has been enforced. For these reasons, the Court determines that these are distinct claims that require consideration of facts outside of the text of Act 1103. The current post-enforcement, as-applied claims could not have been part of the *PhRMA* Case, were not litigated in that facial challenge case, and the current claims may proceed.

B. Analysis Under Rule 12(c)

DCMC also maintains that AstraZeneca's claims fail as a matter of law under the Federal Rule of Civil Procedure 12(c) standard (Dkt. No. 102, at 10). DCMC contends that Act 1103 is not preempted by federal patent laws because it does not adjust 340B drug prices as this Court has ruled and the Eighth Circuit has affirmed (*Id.*, at 19). DCMC next argues that AstraZeneca has not pleaded facts that would give rise to a basis for relief resulting from an alleged violation of the Contracts Clause (*Id.*, at 25). Finally, DCMC asserts that Act 1103 neither forcibly takes property from AstraZeneca nor is a regulatory taking (*Id.*, at 32). The Court disagrees with DCMC and determines that AstraZeneca's claims survive DCMC's Rule 12(c) challenge.

1. Patent Law Preemption

AstraZeneca claims in Count I that Act 1103 is preempted by federal patent laws under a theory of conflict preemption (Dkt. No. 25, ¶ 65). DCMC makes a facial argument, asserting

that Count I should be dismissed because Act 1103 does not cap or fix drug prices, only the federal 340B program does (Dkt. No. 102, at 1).

“Article VI of the Constitution provides that the laws of the United States ‘shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.’” U.S. Const. art. VI, cl. 2. State laws that conflict with federal law are “without effect.” *Capelan v. Lagged Grp., Inc.*, 505 U.S. 504, 516 (1992). Congress may preempt a state law through federal legislation, but where a federal statute does not refer expressly to preemption, Congress may implicitly preempt a state law. *Annex, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376 (2015). Congress may impliedly pre-empt state law “either through ‘field’ preemption or ‘conflict’ preemption.” *Id.* at 376–77. Conflict preemption exists where “‘compliance with both state and federal law is impossible,’ or where ‘the state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’”” *Id.* (quoting *California v. ARC Am. Corp.*, 490 U.S. 93, 100, 101 (1989)).

In the current case, AstraZeneca contends that federal patent law preempts Act 1103 because the patent holder maintains the exclusive right to make pricing decisions about its patented product. AstraZeneca cites *Biotechnology Industry Organization v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007), in which the Federal Circuit held that federal patent law preempted the District of Columbia’s Prescription Drug Excessive Pricing Act of 2005 because the “underlying determination about the proper balance between innovators’ profit and consumer access to medication . . . is exclusively one for Congress to make,” and the local law stood “as an obstacle to the federal patent law’s balance of objectives.” *Id.*

AstraZeneca argues that Act 1103 as applied and enforced against AstraZeneca restricts the prices at which manufacturers can sell their patented drugs by requiring drug manufacturers to

make 340B drugs available for unlimited contract pharmacy sales (Dkt. No. 25, at 20). AstraZeneca highlights that this case, unlike the prior case, is before this Court on a fully developed factual record post-enforcement of Act 1103. AstraZeneca asserts that Act 1103 functions as a price cap for an unlimited number of contract pharmacy sales that impermissibly constrains manufacturers' "opportunity" to take advantage of the benefit of exclusivity conferred by Congress "during the patent's term." *Id.* at 21 (quoting *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007)).

The Court acknowledges that, based solely on the statutory text of Act 1103, this Court ruled and the Eighth Circuit affirmed that the Arkansas law as written did not require manufacturers to provide 340B pricing discounts to contract pharmacies nor does the law set or enforce discount pricing. Act 1103 as written places restrictions on what pharmaceutical manufacturers or third-party logistic providers can restrict or prohibit regarding the acquisition or delivery of 340B drug to a contract pharmacy on a covered entity's behalf. *Pharm. Rsch. & Manufacturers of Am.*, 95 F.4th at 1143.

AstraZeneca alleges that covered entities do not actually retain title to the 340B drugs and that contract pharmacies are actually independent contractors, instead of agents of the covered entities, facts that AstraZeneca claims are different from what the Eighth Circuit based its ruling in the *PhRMA* Case on when reviewing the facial challenge to Act 1103. Facts about the enforcement of Act 1103 as to AstraZeneca were not before the Court in the *PhRMA* Case; those facts were not developed or litigated in that case.

Further, taking AstraZeneca's allegations as true, it has raised a right to relief above a speculative level with respect to Count I. For these reasons, the Court denies DCMC's motion for judgment on the pleadings as to Count I.

2. Contracts Clause Claim

AstraZeneca’s Contracts Clause claim in Count II, like its Takings Clause claim in Count III, does not rest entirely on the pricing issue and is not based solely on the text of the law. The Contracts Clause and Takings Clause claims as asserted in this case are based on how the law is applied to AstraZeneca’s Pharmaceutical Pricing Agreements (“PPAs”)¹ and whether Act 1103 requires a “forced transfer” of AstraZeneca’s property (Dkt. No. 25, at 25–26). These are post-enforcement, as-applied claims.

In Count II, AstraZeneca alleges that Act 1103 violates the Contracts Clause of the U.S. Constitution (Dkt. No. 25, ¶¶ 94–99). Specifically, AstraZeneca alleges that Act 1103 substantially impairs the PPAs it entered to participate in the federal 340B program and that the State of Arkansas has no legitimate justification for requiring unlimited contract pharmacy arrangements (*Id.*). DCMC argues that AstraZeneca has not pleaded facts that support a violation of the Contracts Clause (Dkt. No. 102, at 25).

The Contract Clause of the United States Constitution provides that no state shall “pass any law impairing the Obligation of Contracts.” U.S. Const. art. I, § 10, cl. 1. A three-part test determines whether state action violates the Contract Clause. First the court asks whether “the state law has, in fact, operated as a substantial impairment on pre-existing contractual relationships.” *Am. Fed’n of State, Cnty. & Mun. Emps. v. City of Benton, Arkansas*, 513 F.3d 874, 879 (8th Cir. 2008) (quoting *Equip. Mfrs. Inst. v. Janklow*, 300 F.3d 842, 850 (8th Cir. 2002)).

¹ PPAs are “uniform agreements that recite the responsibilities § 340B imposes . . . on drug manufacturers and the Secretary of HHS.” *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 113 (2011). AstraZeneca’s eligibility to participate in Arkansas’s Medicaid program is conditioned on AstraZeneca’s entry into PPAs for covered drugs purchased by 340B covered entities. *Id.*

The first prong involves a three-part inquiry: “(1) whether there is a contractual relationship; (2) whether a change in law impairs that contractual relationship; and (3) whether the impairment is substantial.” *Gen. Motors Corp v. Romein*, 503 U.S. 181, 186 (1992). If substantial impairment exists, the court will determine whether the state has a “significant and legitimate public purpose behind the regulation.” *Educ. Emps. Credit Union v. Mut. Guar. Corp.*, 50 F.3d 1432, 1438 (8th Cir. 1995) (quoting *Energy Rsrvs. Grp. v. Kan Power & Light Co.*, 459 U.S. 400, 411, (1983)). If there is no significant and legitimate public purpose, the state law is unconstitutional under the Contract Clause. *See Equip. Mfrs. Inst.*, 300 F.3d at 850. However, if the state identifies such a public purpose, the court will consider “whether the adjustment of the rights and responsibilities of contracting parties is based upon reasonable conditions and is of a character appropriate to the public purpose justifying the legislation’s adoption.” *Energy Rsrvs. Grp*, 459 U.S. at 412.

AstraZeneca alleges that it signed a PPA to participate in the federal 340B program (Dkt. No. 25, at 22). A part of the terms of the PPA is the requirement that manufacturers offer discounted drugs only to a specifically delineated set of covered entities (*Id.*). Neither the 340B statute nor the PPA requires drug manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies, according to AstraZeneca (*Id.*). AstraZeneca claims that Act 1103 expands its obligations under the PPA to unlimited contract pharmacies causing a substantial impairment of AstraZeneca’s expectation of the 340B program (*Id.*, at 23). AstraZeneca further argues that the State of Arkansas has no legitimate justification for requiring unlimited contract pharmacy arrangements (*Id.*). AstraZeneca states that its policy already ensures that every covered entity is offered those drugs at a discount and that AstraZeneca’s policies allow a covered entity to designate a single contract pharmacy if it does not have an on-site pharmacy to dispense the 340B drugs

(*Id.*). Additionally, AstraZeneca argues that Act 1103 will advance the economic interest of for-profit entities without a cost-reduction for patients (*Id.*).

Taking AstraZeneca's allegations as true, as the Court must at this stage of the litigation, AstraZeneca has raised a right to relief above a speculative level. AstraZeneca has sufficiently alleged the existence of a contract that would be substantially impaired by enforcement of Act 1103. For these reasons, the Court denies DCMC's motion for judgment on the pleadings as to Count II.

3. Takings Clause Claim

AstraZeneca alleges in Count III that Act 1103 violates both the Takings Clause of the U.S. and Arkansas Constitutions by a physical appropriation of manufacturers' prescription drugs by contract pharmacies and covered entities (Dkt. No. 25, ¶¶ 100–05). Alternatively, AstraZeneca alleges in Count III that, if not a physical appropriation, it would still constitute a regulatory taking (*Id.*). AstraZeneca's Takings Clause claim in Count III does not rest entirely on the pricing issue and is not based solely on the text of the law. The Takings Clause claim as asserted in this case is based on how the law is applied to AstraZeneca in this post-enforcement, as-applied challenge to Act 1103. DCMC argues that, on its face, Act 1103 neither forcibly takes property from AstraZeneca nor constitutes a regulatory taking (Dkt. No. 102, at 32–38).

The Fifth Amendment's Takings Clause, which is applicable to the states under the Fourteenth Amendment, provides: “[N]or shall private property be taken for public use, without just compensation.” U.S. Const. amend. V. The Takings Clause protects property owners from both physical and regulatory takings—the “direct appropriation of property” by governmental actors and imposition of “restriction[s] on the use of property that went ‘too far.’” *Horne v. Dep’t of Agric.*, 576 U.S. 351, 360 (2015) (quoting *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922)).

In either event, “[t]he government must pay for what it takes.” *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 148 (2021).

a. Physical Appropriation

AstraZeneca alleges that Act 1103 takes AstraZeneca’s private property. AstraZeneca contends that Act 1103 forces it to transfer its prescription drugs to private, non-governmental entities—“namely, to contract pharmacies and the covered entities with which they contract.” (Dkt. No. 25, at 25, ¶ 85). AstraZeneca asserts that this forced transfer results in the physical appropriation of its prescription drugs and that, therefore, it constitutes a *per se* taking (*Id.*, at 25). AstraZeneca contends that, since Act 1103 requires transfer to a private entity, no amount of compensation can justify the transfer (*Id.* (citing *Kelo v. City of New London, Conn.*, 545 U.S. 469, 477 (2005))). AstraZeneca argues that, even if the compensation it receives is considered, it is well below the market value (*Id.*).

DCMC asserts that on its face Act 1103 does not forcibly take any property from AstraZeneca or compel a transfer of title to contract pharmacies and that, therefore, AstraZeneca’s argument for a physical appropriation of private property must fail (Dkt. No. 102, at 26–27). Further, DCMC argues that, because AstraZeneca has voluntarily participated in the federal 340B program, this cannot give rise to an unconstitutional taking (*Id.*, at 27).

AstraZeneca acknowledges that it voluntarily entered into the 340B program (Dkt. No. 90, at 40). Further, it acknowledges that, when an entity voluntarily participates in a federal program, it eliminates the possibility that the statute “could result in an imposed taking of private property by the federal government which would give rise to the constitutional right of just compensation,” (*Id.*, at 41). *See Arkansas Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (quoting

Minnesota Ass'n of Health Care Facilities, Inc., 742 F.2d at 446 (8th Cir. 1984)). AstraZeneca voluntarily signed a PPA to participate in the federal 340B program (Dkt. No. 25, at 74–76).

The question raised here, according to AstraZeneca, is whether Act 1103 as applied by the State of Arkansas to AstraZeneca in this post-enforcement, as applied challenge impermissibly regulates the distribution of the drugs in Arkansas as part of this program and constitutes a taking by the State of Arkansas, with which AstraZeneca did not voluntarily enter into any agreement or program (*Id.*, at 25, ¶ 86). AstraZeneca makes argument in its briefing as to why its participation should be considered involuntary with respect to Act 1103 and its impact as to AstraZeneca.

AstraZeneca has sufficiently alleged a claim under the Takings Clause as to physical appropriation, when the Court accepts as true AstraZeneca's allegations. For these reasons, the Court denies DCMC's motion for judgment on the pleadings of AstraZeneca's Count III to the extent Count III is premised on an alleged physical appropriation claim.

b. Unconstitutional Regulatory Taking

DCMC asserts that AstraZeneca has failed to allege facts showing a taking under the *Penn Central* Test (Dkt. No. 102, at 34–38). AstraZeneca contends that Act 1103: (1) has a profound economic impact on the value of the property subject to the law; (2) significantly interferes with its investment-backed expectations; and (3) forces AstraZeneca to transfer title to its property, depriving it of full use and enjoyment of said property (Dkt. No. 90, at 45–49).

The default test for determining whether a regulation constitutes a taking is known as the *Penn Central* Test. The *Penn Central* Court crafted a test that focuses largely “upon the particular circumstances [in each] case.” *Becker v. City of Hillsboro, Mo.*, 125 F.4th 844, 852 (8th Cir. 2025) (quoting *Penn Cent. Transp. Co. v. N.Y.C.*, 438 U.S. 104, 130–31 (1978)). Under the *Penn Central* balancing test, courts consider: (1) “the economic impact of the regulation on the

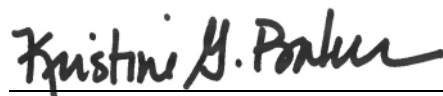
claimant,” (2) “the extent to which the regulation has interfered with distinct investment-back expectations,” and (3) “the character of the government action.” *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 130–31 (1978).

AstraZeneca alleges that the same facts giving rise to the physical appropriation claim also give rise to the regulatory taking claim, if Act 1103 does not involve actual physical appropriation (Dkt. No. 25, at 25, ¶ 88). At this stage of the proceeding, this Court agrees. AstraZeneca has sufficiently alleged a claim under the Takings Clause as to a regulatory taking to survive DCMC’s motion for judgment on the pleadings. For these reasons, the Court denies DCMC’s motion for judgment on the pleadings of AstraZeneca’s Count III to the extent Count III is premised on an alleged regulatory taking claim.

IV. Conclusion

For these reasons, the Court denies DCMC’s motion for judgment on the pleadings (Dkt. No. 84). The Court denies as moot AstraZeneca’s motion to strike the declaration of Rand Booth (Dkt. No. 103).

It is so ordered this 30th day of September, 2025.



Kristine G. Baker
Chief United States District Judge

**IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION**

ASTRAZENECA PHARMACEUTICALS LP

PLAINTIFF

v.

Case No. 4:24-cv-00268-KGB

**JIMMY HARRIS, in his official capacity
as Commissioner of the Arkansas
Insurance Department**

DEFENDANT

DALLAS COUNTY MEDICAL CENTER

INTERVENOR

ORDER

Pending before the Court are a motion for judgment on the pleadings filed by intervenor Dallas County Medical Center (“DCMC”) (Dkt. No. 84) and a motion to strike the declaration of Rand Booth filed by plaintiff AstraZeneca Pharmaceuticals LP (“AstraZeneca”) (Dkt. No. 103). AstraZeneca has responded, and DCMC and defendant Alan McClain, in his official capacity as Commissioner of the Arkansas Insurance Department (“Commissioner”), have replied (Dkt. Nos. 90, 102, 110). For the following reasons, the Court denies DCMC’s motion for judgment on the pleadings (Dkt. No. 84), and the Court denies as moot AstraZeneca’s motion to strike (Dkt. No. 103).

I. Background

This case arises out of the Arkansas legislature’s passage of Act 1103 of 2021 (“Act 1103”), Ark. Code Ann. § 23-92-601 *et seq.*, which addresses the delivery of 340B drugs to contract pharmacies in Arkansas. Section 340B is a federal prescription drug program that requires pharmaceutical manufacturers to provide qualified health care providers, referred to as “covered entities,” with pricing discounts on certain drugs prescribed to individuals and families whose income falls below the federal poverty level. 42 U.S.C. § 256b(a)(1); 42 U.S.C. § 1396r-8(a)(1). Covered entities have contracted with outside pharmacies for the distribution of 340B drugs. Act 1103 protects covered entities and their patients from drug manufacturers’ restrictions on the

number of contract pharmacies a covered entity can use and still receive discount pricing under the 340B plan. Ark. Code Ann. § 23-92-60.

In 2020, a number of pharmaceutical companies imposed restrictions and limitations on the distribution of Section 340B discounted drugs to contract pharmacies. *See, e.g., Sanofi Policy, SANOFI* (Feb. 1, 2021), https://340besp.com/sanofi-policy-2021-02-02-09_18_19.pdf. In response, the U.S. Department of Health and Human Services (“HHS”) issued an opinion stating that “covered entities under the 340B program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients.” *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 52 (D. Del. 2021). Further, HHS concluded that the “plain meaning” of Section 340B precluded participating pharmaceutical companies from restricting or otherwise limiting contracts between covered entities and outside, retail pharmacies. *Id.* at 52–53. AstraZeneca and other pharmaceutical companies challenged HHS’s contract pharmacy opinion and prevailed in the Third Circuit in *Sanofi Aventis U.S. LLC v. U.S. Dep’t of Health and Human Services*, 58 F.4th 696 (3d Cir. 2023). In that case, the Third Circuit held that Section 340B is silent with respect to contract pharmacies and that, therefore, HHS lacked the statutory authority to issue its opinion restricting the ability of participating pharmaceutical companies to adopt policies on the distribution of discounted drugs to contract pharmacies. *Id.* at 703–06.

Arkansas enacted Act 1103, which “prohibits pharmaceutical manufacturers from interfering in a covered entity’s agreement with a contract pharmacy by denying the pharmacy access to a covered entity’s 340B drugs” and “prohibits pharmaceutical manufacturers from interfering in a covered entity’s agreement with a contract pharmacy by denying 340B drug pricing

to covered entities who use contract pharmacies for distribution.” *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024) (citing Ark. Code Ann. § 23-92-604).

In 2022, an association of pharmaceutical manufacturers sought an injunction against enforcement of Act 1103 on a theory that Section 340B preempts it. *Id.* at 1139–40. They mounted a facial, pre-enforcement challenge. This Court and the Eighth Circuit disagreed with the position advocated by the association of pharmaceutical manufacturers. *Id.* The Eighth Circuit held that “the 340B Program is not ‘so pervasive . . . that Congress left no room for the States to supplement it,’” given that the statute “‘is silent about delivery’ of drugs to patients.” *Id.* at 1143 (quoting *Sanofi Aventis*, 58 F.4th at 703) (other quotation marks and citation omitted). Additionally, because the Arkansas law “does not require manufacturers to provide 340B pricing discounts to contract pharmacies,” and “does not set or enforce discount pricing,” the Eighth Circuit found that “the delivery of a covered entity’s 340B drugs to contract pharmacies for dispensing creates no obstacle” to the statute’s purpose. *Id.* at 1145. In fact, the Eighth Circuit observed that the Arkansas law “assists in fulfilling the purpose of 340B” because it facilitates the distribution and dispensation of discounted 340B drugs. *Id.*

AstraZeneca’s operative complaint alleges three counts seeking declaratory relief that Act 1103 is unconstitutional and injunctive relief barring the enforcement of Act 1103 (Dkt. No. 25). AstraZeneca now maintains an as-applied, post-enforcement challenge. Count I alleges that Act 1103 is preempted by federal patent laws under the Supremacy Clause (*Id.*, ¶¶ 90–93). Count II alleges that Act 1103 violates the Contracts Clause of the U.S. Constitution (*Id.*, ¶¶ 94–99), and Count III alleges that Act 1103 violates the Takings Clause of the U.S. Constitution (*Id.*, ¶¶ 100–05).

AstraZeneca is a limited partnership organized under the laws of Delaware with its principal place of business in Wilmington, Delaware (*Id.*, ¶ 14). Commissioner is a resident of Arkansas who is responsible for administering and enforcing the provisions of Act 1103. (*Id.*, ¶ 15). DCMC is a nonprofit, government-funded hospital located in Fordyce, Arkansas (Dkt. No. 30, at 12). DCMC has been designated under the Medicare program as a critical access hospital (“CAH”) (*Id.*, at 11). Based on its CAH status, DCMC participates as a covered entity under the 340B program. (*Id.*, at 12).

In its motion for judgment on the pleadings, DCMC contends that AstraZeneca’s claims are barred by claim and issue preclusion because all of its claims could have been brought in the *PhRMA* case and because the issue of whether Act 1103 affects drug pricing was settled in the *PhRMA* case (Dkt. No. 84). AstraZeneca responds that DCMC and AstraZeneca were not involved in the previous litigation, nor were they in privity with any party there (Dkt. No. 90). Additionally, AstraZeneca contends that its claims in this case are different because those claims are based on how ACT 1103 is applied to contract pharmacy policies instead of a facial constitutional challenge (*Id.*).

DCMC argues that, even if AstraZeneca’s claims are not precluded, they fail as a matter of law (Dkt. No. 102). DCMC contends that Act 1103 is not preempted by federal patent laws because it does not adjust 340B drug prices as this Court has ruled and the Eighth Circuit has affirmed (*Id.*, at 19). DCMC next argues that AstraZeneca has not pleaded facts that would give rise to a basis for relief resulting from an alleged violation of the Contracts Clause (*Id.*, at 25). Finally, DCMC asserts that Act 1103 neither forcibly takes property from AstraZeneca nor is a regulatory taking (*Id.*, at 32).

II. Applicable Law

Federal Rule of Civil Procedure 12 provides that a party may seek judgment on the pleadings. Fed. R. Civ. P. 12(c). “A motion for judgment on the pleadings will be granted only where the moving party has clearly established that no material issue of fact remains and the moving party is entitled to judgment as a matter of law.” *Waldron v. Boeing Co.*, 388 F.3d 591, 593 (8th Cir. 2004) (citations omitted).

A motion under Federal Rule of Civil Procedure 12(c) is governed by the same standards as a motion under Federal Rule of Civil Procedure 12(b)(6): “a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Clemons v. Crawford*, 585 F.3d 1119, 1124 (8th Cir. 2009) (citing *Ashley Cnty., Ark. v. Pfizer*, 552 F.3d 659, 665 (8th Cir. 2009)). Further, the court “view[s] all facts pleaded by the nonmoving party as true and grants all reasonable inferences in favor of that party.” *Poehl v. Countrywide Home Loans, Inc.*, 528 F.3d 1093, 1096 (8th Cir. 2008) (citing *Syverson v. FirePond, Inc.*, 383 F.3d 745, 749 (8th Cir. 2004)). While the court’s review is generally limited to the pleadings in this context, the court may properly consider “matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint.” *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999).

III. Analysis

DCMC contends that AstraZeneca’s amended complaint should be barred by *res judicata*—both claim and issue preclusion (Dkt. No. 84, at 2). DCMC also maintains that AstraZeneca’s claims fail as a matter of law under the Federal Rule of Civil Procedure 12(c) standard (*Id.*, at 1).

A. Analysis Of Claim Or Issue Preclusion

Under federal common law, the doctrine of *res judicata* or claim preclusion, applies when: “(1) the first suit resulted in a final judgment on the merits; (2) the first suit was based on proper jurisdiction; (3) both suits involve the same parties (or those in privity with them); and (4) both suits are based upon the same claims or causes of action.” *Costner v. URS Consultants, Inc.*, 153 F.3d 667, 673 (8th Cir. 1998). “[W]hether two claims are the same for *res judicata* purposes depends on whether the claims arise out of the same nucleus of operative fact or are based upon the same factual predicate.” *Elbert v. Carter*, 903 F.3d 779, 782 (8th Cir. 2018) (quoting *Murphy v. Jones*, 877 F.2d 682, 684–85 (8th Cir. 1989)). Under the doctrine of *res judicata*, “a final judgment on the merits of an action precludes the parties or their privies from re-litigating issues that were or could have been raised in that action.” *Allen v. McCurry*, 449 U.S. 90, 94 (1980).

The doctrine of collateral estoppel, or issue preclusion, provides that “when an issue of ultimate fact has been determined by a valid and final judgment, that issue cannot again be litigated between the same parties in another lawsuit.” *United States v. Brekke*, 97 F.3d 1043, 1049 (8th Cir. 1996). Courts in the Eighth Circuit examine five factors to determine whether collateral estoppel applies to a particular case:

- (1) the party sought to be precluded in the second suit must have been a party, or in privity with a party, to the original lawsuit;
- (2) the issue sought to be precluded must be the same as the issue involved in the prior action;
- (3) the issue sought to be precluded must have been actually litigated in the prior action;
- (4) the issue sought to be precluded must have been determined by a valid and final judgment; and
- (5) the determination in the prior action must have been essential to the prior judgment.

Estrada-Rodriguez v. Lynch, 825 F.3d 397, 402 (8th Cir. 2016).

DCMC contends that all of AstraZeneca's claims should have been brought in the *PhRMA* case (Dkt. No. 85, at 26). Further, DCMC argues that, since the issue of whether Act 1103 improperly regulates drug pricing was settled in *PhARMA*, the issue cannot be re-litigated here, so any claim that relies on the pricing issue should be dismissed (*Id.*, at 27). AstraZeneca disputes privity to the *PhRMA* parties and whether the claims and issues arise from the same causes of action and facts (Dkt No. 90).

As an initial matter, DCMC provided an affidavit from Commissioner's counsel, Rand Booth, stating the Commissioner supports DCMC's motion for judgment on the pleadings (Dkt. No. 102–1). AstraZeneca moves to strike the declaration (Dkt. No. 103). In response, DCMC concedes that the declaration “is not critical to [DCMC's] motion, and in the interest of efficiency, [DCMC] agrees that this Court should disregard the Declaration in ruling on [DCMC]'s motion.” (Dkt. No. 110, at 2). Accordingly, the Court denies as moot the motion to strike (Dkt. No. 103). The Court will not consider the declaration in considering DCMC's motion.

1. Privity

AstraZeneca contends that, since DCMC was not a party to the *PhRMA* litigation, DCMC cannot invoke that litigation as a basis for claim or issue preclusion in this case (Dkt. No. 90, at 22 (citing *United States v. Metropolitan St. Louis Sewer District*, 952 F.2d 1040 (8th Cir. 1992))). In response to AstraZeneca's privity arguments regarding DCMC, DCMC contends that, even though it was not a party to *PhRMA v. McClain*, Case No. 4:21-cv-00864-BRW (Mar. 28, 2022) (“*PhRMA Case*”), it was in privity with the intervenors in the *PhRMA Case* (Dkt. No. 102, at 10–12).

Claim or issue preclusion may be raised by a nonparty that is in privity with a party to the original lawsuit. “[I]n certain limited circumstances” a nonparty to a prior suit may be considered

in privity with a party if the nonparty was “‘adequately represented’ by someone with the same interests who [wa]s a party” to the prior suit. *Midwest Disability Initiative v. JANS Enters., Inc.*, 929 F.3d 603, 607 (8th Cir. 2019) (citation omitted). This “adequate representation” requirement is satisfied if: (1) the interests of the two parties are aligned; and (2) the original party understood itself to be acting in a representative capacity. *Id.*

a. DCMC

The intervenors in the *PhRMA* Case were Community Health Centers of Arkansas and Piggott Community Hospital (“*PhRMA* Intervenors”). See *PhRMA v. McClain*, Case No. 4:21-cv-00864-BRW (Mar. 28, 2022), Dkt. No. 18, at 23. *PhRMA* Intervenors represented all of the safety net hospitals and clinics in Arkansas participating in the 340B program, which included the DCMC in this case. *Id.* *PhRMA* Intervenors successfully defended against a pre-enforcement facial challenge to the constitutionality of Act 1103 on preemption grounds. Based on the record in both cases, the Court determines that the interests of the *PhRMA* Intervenors and DCMC in this case are aligned and that the *PhRMA* Intervenors knowingly represented the interests of all Arkansas covered entities. *PhRMA* Intervenors satisfy the requirement of adequate representation for purposes of privity. Accordingly, this Court concludes that the *PhRMA* Intervenors and DCMC are in privity and that DCMC may invoke claim or issue preclusion despite not having been a party in the *PhRMA* Case.

b. AstraZeneca

The Court notes that AstraZeneca does not concede its privity with plaintiff in the *PhRMA* Case. AstraZeneca makes no substantive privity argument with respect to AstraZeneca’s relationship with plaintiff in the *PhRMA* Case in its pleadings. This Court proceeds to analyze

these legal issues assuming without deciding, and applying the same rationale as articulated with respect to DCMC, that AstraZeneca was in privity with plaintiff in the *PhRMA* Case.

2. Claims

In addition to a privity requirement, application of claim or issue preclusion depends on whether both suits are based on the same claims or causes of action: “a claim is barred by res judicata if it arises out of the same nucleus of operative facts as the prior claim.” *Yankton Sioux Tribe v. U.S. Dept. of Health and Human Servs.*, 533 F.3d 634, 641 (8th Cir. 2008) (quotation omitted); see also *Midwest Disability Initiative v. JANS Enters., Inc.*, 929 F.3d 603, 609–10 (8th Cir. 2019). “[W]hether two claims are the same for res judicata purposes depends on whether the claims arise out of the same nucleus of operative fact or are based upon the same factual predicate.” *Murphy v. Jones*, 877 F.2d 682, 684–85 (8th Cir. 1989).

Further, the issue sought to be precluded must have been actually litigated in the prior action for collateral estoppel to apply. To assess whether an issue has been “actually litigated,” the Eighth Circuit provides the following guidance:

The inquiry must always be as to the point or question actually litigated and determined in the original action, not what might have been thus litigated and determined. An issue lurking in the record but not raised or decided is not actually litigated. A party may choose not to litigate a particular issue for various reasons, including cost, strategy, and the difficulty of obtaining evidence.

We thus agree with other circuits that for an issue to be “actually litigated,” the issue must have been “raised, contested, and submitted for determination” in the prior proceeding, and it must be determined.

Fofana v. Mayorkas, 4 F.4th 668, 671 (8th Cir. 2021) (internal citations omitted).

DCMC contends that the operative fact in both cases is the passage of Act 1103; DCMC makes a facial argument. AstraZeneca asserts that the claims in the current case rely on more

than the passage of the law and include how the law is applied to AstraZeneca's specific policies in Arkansas; AstraZeneca makes an as-applied argument.

Upon review of AstraZeneca's claims, the Court determines that none of AstraZeneca's current claims are barred by claim or issue preclusion. All parties concede that the *PhRMA* Case was a pre-enforcement, facial challenge to Act 1103. Further, all parties acknowledge that this current suit involves a post-enforcement, as-applied challenge to Act 1103 by AstraZeneca against whom Act 1103 now has been enforced. For these reasons, the Court determines that these are distinct claims that require consideration of facts outside of the text of Act 1103. The current post-enforcement, as-applied claims could not have been part of the *PhRMA* Case, were not litigated in that facial challenge case, and the current claims may proceed.

B. Analysis Under Rule 12(c)

DCMC also maintains that AstraZeneca's claims fail as a matter of law under the Federal Rule of Civil Procedure 12(c) standard (Dkt. No. 102, at 10). DCMC contends that Act 1103 is not preempted by federal patent laws because it does not adjust 340B drug prices as this Court has ruled and the Eighth Circuit has affirmed (*Id.*, at 19). DCMC next argues that AstraZeneca has not pleaded facts that would give rise to a basis for relief resulting from an alleged violation of the Contracts Clause (*Id.*, at 25). Finally, DCMC asserts that Act 1103 neither forcibly takes property from AstraZeneca nor is a regulatory taking (*Id.*, at 32). The Court disagrees with DCMC and determines that AstraZeneca's claims survive DCMC's Rule 12(c) challenge.

1. Patent Law Preemption

AstraZeneca claims in Count I that Act 1103 is preempted by federal patent laws under a theory of conflict preemption (Dkt. No. 25, ¶ 65). DCMC makes a facial argument, asserting

that Count I should be dismissed because Act 1103 does not cap or fix drug prices, only the federal 340B program does (Dkt. No. 102, at 1).

“Article VI of the Constitution provides that the laws of the United States ‘shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.’” U.S. Const. art. VI, cl. 2. State laws that conflict with federal law are “without effect.” *Capelan v. Lagged Grp., Inc.*, 505 U.S. 504, 516 (1992). Congress may preempt a state law through federal legislation, but where a federal statute does not refer expressly to preemption, Congress may implicitly preempt a state law. *Annex, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376 (2015). Congress may impliedly pre-empt state law “either through ‘field’ preemption or ‘conflict’ preemption.” *Id.* at 376–77. Conflict preemption exists where “‘compliance with both state and federal law is impossible,’ or where ‘the state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’”” *Id.* (quoting *California v. ARC Am. Corp.*, 490 U.S. 93, 100, 101 (1989)).

In the current case, AstraZeneca contends that federal patent law preempts Act 1103 because the patent holder maintains the exclusive right to make pricing decisions about its patented product. AstraZeneca cites *Biotechnology Industry Organization v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007), in which the Federal Circuit held that federal patent law preempted the District of Columbia’s Prescription Drug Excessive Pricing Act of 2005 because the “underlying determination about the proper balance between innovators’ profit and consumer access to medication . . . is exclusively one for Congress to make,” and the local law stood “as an obstacle to the federal patent law’s balance of objectives.” *Id.*

AstraZeneca argues that Act 1103 as applied and enforced against AstraZeneca restricts the prices at which manufacturers can sell their patented drugs by requiring drug manufacturers to

make 340B drugs available for unlimited contract pharmacy sales (Dkt. No. 25, at 20). AstraZeneca highlights that this case, unlike the prior case, is before this Court on a fully developed factual record post-enforcement of Act 1103. AstraZeneca asserts that Act 1103 functions as a price cap for an unlimited number of contract pharmacy sales that impermissibly constrains manufacturers' "opportunity" to take advantage of the benefit of exclusivity conferred by Congress "during the patent's term." *Id.* at 21 (quoting *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007)).

The Court acknowledges that, based solely on the statutory text of Act 1103, this Court ruled and the Eighth Circuit affirmed that the Arkansas law as written did not require manufacturers to provide 340B pricing discounts to contract pharmacies nor does the law set or enforce discount pricing. Act 1103 as written places restrictions on what pharmaceutical manufacturers or third-party logistic providers can restrict or prohibit regarding the acquisition or delivery of 340B drug to a contract pharmacy on a covered entity's behalf. *Pharm. Rsch. & Manufacturers of Am.*, 95 F.4th at 1143.

AstraZeneca alleges that covered entities do not actually retain title to the 340B drugs and that contract pharmacies are actually independent contractors, instead of agents of the covered entities, facts that AstraZeneca claims are different from what the Eighth Circuit based its ruling in the *PhRMA* Case on when reviewing the facial challenge to Act 1103. Facts about the enforcement of Act 1103 as to AstraZeneca were not before the Court in the *PhRMA* Case; those facts were not developed or litigated in that case.

Further, taking AstraZeneca's allegations as true, it has raised a right to relief above a speculative level with respect to Count I. For these reasons, the Court denies DCMC's motion for judgment on the pleadings as to Count I.

2. Contracts Clause Claim

AstraZeneca’s Contracts Clause claim in Count II, like its Takings Clause claim in Count III, does not rest entirely on the pricing issue and is not based solely on the text of the law. The Contracts Clause and Takings Clause claims as asserted in this case are based on how the law is applied to AstraZeneca’s Pharmaceutical Pricing Agreements (“PPAs”)¹ and whether Act 1103 requires a “forced transfer” of AstraZeneca’s property (Dkt. No. 25, at 25–26). These are post-enforcement, as-applied claims.

In Count II, AstraZeneca alleges that Act 1103 violates the Contracts Clause of the U.S. Constitution (Dkt. No. 25, ¶¶ 94–99). Specifically, AstraZeneca alleges that Act 1103 substantially impairs the PPAs it entered to participate in the federal 340B program and that the State of Arkansas has no legitimate justification for requiring unlimited contract pharmacy arrangements (*Id.*). DCMC argues that AstraZeneca has not pleaded facts that support a violation of the Contracts Clause (Dkt. No. 102, at 25).

The Contract Clause of the United States Constitution provides that no state shall “pass any law impairing the Obligation of Contracts.” U.S. Const. art. I, § 10, cl. 1. A three-part test determines whether state action violates the Contract Clause. First the court asks whether “the state law has, in fact, operated as a substantial impairment on pre-existing contractual relationships.” *Am. Fed’n of State, Cnty. & Mun. Emps. v. City of Benton, Arkansas*, 513 F.3d 874, 879 (8th Cir. 2008) (quoting *Equip. Mfrs. Inst. v. Janklow*, 300 F.3d 842, 850 (8th Cir. 2002)).

¹ PPAs are “uniform agreements that recite the responsibilities § 340B imposes . . . on drug manufacturers and the Secretary of HHS.” *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 113 (2011). AstraZeneca’s eligibility to participate in Arkansas’s Medicaid program is conditioned on AstraZeneca’s entry into PPAs for covered drugs purchased by 340B covered entities. *Id.*

The first prong involves a three-part inquiry: “(1) whether there is a contractual relationship; (2) whether a change in law impairs that contractual relationship; and (3) whether the impairment is substantial.” *Gen. Motors Corp v. Romein*, 503 U.S. 181, 186 (1992). If substantial impairment exists, the court will determine whether the state has a “significant and legitimate public purpose behind the regulation.” *Educ. Emps. Credit Union v. Mut. Guar. Corp.*, 50 F.3d 1432, 1438 (8th Cir. 1995) (quoting *Energy Rsrvs. Grp. v. Kan Power & Light Co.*, 459 U.S. 400, 411, (1983)). If there is no significant and legitimate public purpose, the state law is unconstitutional under the Contract Clause. *See Equip. Mfrs. Inst.*, 300 F.3d at 850. However, if the state identifies such a public purpose, the court will consider “whether the adjustment of the rights and responsibilities of contracting parties is based upon reasonable conditions and is of a character appropriate to the public purpose justifying the legislation’s adoption.” *Energy Rsrvs. Grp*, 459 U.S. at 412.

AstraZeneca alleges that it signed a PPA to participate in the federal 340B program (Dkt. No. 25, at 22). A part of the terms of the PPA is the requirement that manufacturers offer discounted drugs only to a specifically delineated set of covered entities (*Id.*). Neither the 340B statute nor the PPA requires drug manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies, according to AstraZeneca (*Id.*). AstraZeneca claims that Act 1103 expands its obligations under the PPA to unlimited contract pharmacies causing a substantial impairment of AstraZeneca’s expectation of the 340B program (*Id.*, at 23). AstraZeneca further argues that the State of Arkansas has no legitimate justification for requiring unlimited contract pharmacy arrangements (*Id.*). AstraZeneca states that its policy already ensures that every covered entity is offered those drugs at a discount and that AstraZeneca’s policies allow a covered entity to designate a single contract pharmacy if it does not have an on-site pharmacy to dispense the 340B drugs

(*Id.*). Additionally, AstraZeneca argues that Act 1103 will advance the economic interest of for-profit entities without a cost-reduction for patients (*Id.*).

Taking AstraZeneca’s allegations as true, as the Court must at this stage of the litigation, AstraZeneca has raised a right to relief above a speculative level. AstraZeneca has sufficiently alleged the existence of a contract that would be substantially impaired by enforcement of Act 1103. For these reasons, the Court denies DCMC’s motion for judgment on the pleadings as to Count II.

3. Takings Clause Claim

AstraZeneca alleges in Count III that Act 1103 violates both the Takings Clause of the U.S. and Arkansas Constitutions by a physical appropriation of manufacturers’ prescription drugs by contract pharmacies and covered entities (Dkt. No. 25, ¶¶ 100–05). Alternatively, AstraZeneca alleges in Count III that, if not a physical appropriation, it would still constitute a regulatory taking (*Id.*). AstraZeneca’s Takings Clause claim in Count III does not rest entirely on the pricing issue and is not based solely on the text of the law. The Takings Clause claim as asserted in this case is based on how the law is applied to AstraZeneca in this post-enforcement, as-applied challenge to Act 1103. DCMC argues that, on its face, Act 1103 neither forcibly takes property from AstraZeneca nor constitutes a regulatory taking (Dkt. No. 102, at 32–38).

The Fifth Amendment’s Takings Clause, which is applicable to the states under the Fourteenth Amendment, provides: “[N]or shall private property be taken for public use, without just compensation.” U.S. Const. amend. V. The Takings Clause protects property owners from both physical and regulatory takings—the “direct appropriation of property” by governmental actors and imposition of “restriction[s] on the use of property that went ‘too far.’” *Horne v. Dep’t of Agric.*, 576 U.S. 351, 360 (2015) (quoting *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922)).

In either event, “[t]he government must pay for what it takes.” *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 148 (2021).

a. Physical Appropriation

AstraZeneca alleges that Act 1103 takes AstraZeneca’s private property. AstraZeneca contends that Act 1103 forces it to transfer its prescription drugs to private, non-governmental entities—“namely, to contract pharmacies and the covered entities with which they contract.” (Dkt. No. 25, at 25, ¶ 85). AstraZeneca asserts that this forced transfer results in the physical appropriation of its prescription drugs and that, therefore, it constitutes a *per se* taking (*Id.*, at 25). AstraZeneca contends that, since Act 1103 requires transfer to a private entity, no amount of compensation can justify the transfer (*Id.* (citing *Kelo v. City of New London, Conn.*, 545 U.S. 469, 477 (2005)). AstraZeneca argues that, even if the compensation it receives is considered, it is well below the market value (*Id.*).

DCMC asserts that on its face Act 1103 does not forcibly take any property from AstraZeneca or compel a transfer of title to contract pharmacies and that, therefore, AstraZeneca’s argument for a physical appropriation of private property must fail (Dkt. No. 102, at 26–27). Further, DCMC argues that, because AstraZeneca has voluntarily participated in the federal 340B program, this cannot give rise to an unconstitutional taking (*Id.*, at 27).

AstraZeneca acknowledges that it voluntarily entered into the 340B program (Dkt. No. 90, at 40). Further, it acknowledges that, when an entity voluntarily participates in a federal program, it eliminates the possibility that the statute “could result in an imposed taking of private property by the federal government which would give rise to the constitutional right of just compensation,” (*Id.*, at 41). *See Arkansas Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (quoting

Minnesota Ass'n of Health Care Facilities, Inc., 742 F.2d at 446 (8th Cir. 1984)). AstraZeneca voluntarily signed a PPA to participate in the federal 340B program (Dkt. No. 25, at 74–76).

The question raised here, according to AstraZeneca, is whether Act 1103 as applied by the State of Arkansas to AstraZeneca in this post-enforcement, as applied challenge impermissibly regulates the distribution of the drugs in Arkansas as part of this program and constitutes a taking by the State of Arkansas, with which AstraZeneca did not voluntarily enter into any agreement or program (*Id.*, at 25, ¶ 86). AstraZeneca makes argument in its briefing as to why its participation should be considered involuntary with respect to Act 1103 and its impact as to AstraZeneca.

AstraZeneca has sufficiently alleged a claim under the Takings Clause as to physical appropriation, when the Court accepts as true AstraZeneca's allegations. For these reasons, the Court denies DCMC's motion for judgment on the pleadings of AstraZeneca's Count III to the extent Count III is premised on an alleged physical appropriation claim.

b. Unconstitutional Regulatory Taking

DCMC asserts that AstraZeneca has failed to allege facts showing a taking under the *Penn Central* Test (Dkt. No. 102, at 34–38). AstraZeneca contends that Act 1103: (1) has a profound economic impact on the value of the property subject to the law; (2) significantly interferes with its investment-backed expectations; and (3) forces AstraZeneca to transfer title to its property, depriving it of full use and enjoyment of said property (Dkt. No. 90, at 45–49).

The default test for determining whether a regulation constitutes a taking is known as the *Penn Central* Test. The *Penn Central* Court crafted a test that focuses largely “upon the particular circumstances [in each] case.” *Becker v. City of Hillsboro, Mo.*, 125 F.4th 844, 852 (8th Cir. 2025) (quoting *Penn Cent. Transp. Co. v. N.Y.C.*, 438 U.S. 104, 130–31 (1978)). Under the *Penn Central* balancing test, courts consider: (1) “the economic impact of the regulation on the

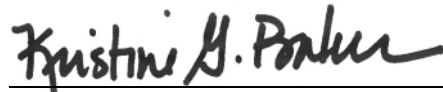
claimant,” (2) “the extent to which the regulation has interfered with distinct investment-back expectations,” and (3) “the character of the government action.” *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 130–31 (1978).

AstraZeneca alleges that the same facts giving rise to the physical appropriation claim also give rise to the regulatory taking claim, if Act 1103 does not involve actual physical appropriation (Dkt. No. 25, at 25, ¶ 88). At this stage of the proceeding, this Court agrees. AstraZeneca has sufficiently alleged a claim under the Takings Clause as to a regulatory taking to survive DCMC’s motion for judgment on the pleadings. For these reasons, the Court denies DCMC’s motion for judgment on the pleadings of AstraZeneca’s Count III to the extent Count III is premised on an alleged regulatory taking claim.

IV. Conclusion

For these reasons, the Court denies DCMC’s motion for judgment on the pleadings (Dkt. No. 84). The Court denies as moot AstraZeneca’s motion to strike the declaration of Rand Booth (Dkt. No. 103).

It is so ordered this 30th day of September, 2025.



Kristine G. Baker
Chief United States District Judge